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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/649,234

08/27/2003

Nobuko Uchida

17810-518 (SCI-18)

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7590

10/25/2006

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT

PAPER NUMBER

1649

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/649,234

Applicant(s)

UCHIDA ET AL.

Examiner

Robert C. Hayes, Ph.D.

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-17, 21, 23-29, 44 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14, 17 and 29 is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 13, 15, 16, 21, 23-28, 44 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10/4/06.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. The amendment filed on 8/14/06 has been entered.
2. The rejection of claims 7 & 13 under 35 U.S.C. 112, first paragraph, for not describing the appropriate ATCC numbers and required Deposit information critical or essential to the practice of the invention is withdrawn due to the amendment of the claims, or due to the amendment to the specification.
3. The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting a broad range or limitation together with a narrow range is withdrawn due to the amendment of the claim.
4. The rejection of claims 7 & 8 under 35 U.S.C. 112, second paragraph, is withdrawn due to the amendment of the claims.
5. The rejection of claims 1-13 under 35 U.S.C. 112, second paragraph, as being incomplete is withdrawn due to the amendment or cancellation of the claims.
6. The rejection of claims 21-22 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn due to the amendment or cancellation of the claims.

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7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Applicants' arguments filed 8/14/06 have been fully considered, but are not deemed to be fully persuasive.

9. Claims 14, 17 & 29 are allowed. However, note that claims 21 & 23 recite "progenitors" on line 2, which do not "initiate neurospheres" unlike the CNS-SCs, which therefore is rejected under 35 U.S.C. 112, first paragraph with dependent claims 24-27, and claim 28. Accordingly, deletion of the recitation "which can initiate neurospheres (NS-IC)" in claims 21 & 23 will place claims 21 & 23-27 in condition for allowance, and obviate this particular rejection of claim 28.

10. Claim 44 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The appropriate ATCC numbers and required Deposit information critical or essential to the practice of the invention, as it relates to monoclonal antibodies SC111, but not included in the claim(s) is not enabled by the disclosure, similar to that previously made of reocrd. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

In particular, no ATCC number, nor date of deposits to the ATCC, was provided in the amendment to the specification for monoclonal antibody SC111. See 37 CFR 1.802.

11. Claims 1-9, 12, 15-16, 21, 23-27, 28 & 44-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing a

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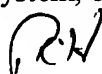
population of enriched human CNS stem cells using identifiable/deposited antibodies, does not reasonably provide enablement for methods of isolating enriched populations of human CNS stem cells using unknown or uncharacterized "reagent[s] that specifically binds to the CD49f antigen", and/or that no longer bind to a CD24 antigen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reason amde of record in Paper No: 20060417, and as follows.

In contrast to Applicants' arguments on pages 11-12 of the response, an invitation for others to make the required monoclonal antibodies to practice the claimed methods does not reasonably enable the current invention without further defined structural characteristics, for the reasons previously made of record (i.e., as it relates to unknown monoclonal antibodies that bind CD49f' or to CD133, or to CD24).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.
October 19, 2006

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER